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| EXAMINER | |
|---|---|
| ROBERTS, LEZAH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/530,558 | TAKEI ET AL. | |
| | Examiner | Art Unit | |
| | Lezah W. Roberts | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *June 13, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,6-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

This Office Action is in Response to the Amendment filed June 13, 2006. All previous rejections have been withdrawn unless state below. All new rejections are necessitated by amendment.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claims*

**Claim Rejections - 35 USC § 112 – New Matter**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 and 12-15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims use the phrase "different from said coating composition". This phrase does not appear to have support in Applicant's instant disclosure therefore it is new matter. It also cannot be determined what is meant by "different" such as how the compositions are different.

Suggested language: "...comprising a combination of 1) a primer composition... 2) a coating composition... and 3) a surface smoothing composition.

**Claim Rejections - 35 USC § 103 – Obviousness (New rejections)**

1) Claims 1-2 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsunae et al. (US 6,174,935).

Matsunae et al. disclose dental adhesive kits comprising a self-etching primer and a bonding agent. The self-etching primer includes a methacrylate or acrylate ranging form 1.0 to 50% of the composition. The methacrylate or acrylate have an acidic group and have at least one unsaturated double bond. The compositions comprise a water-soluble organic solvent, which makes up 1.0 to 98% by weight of the composition. Water is also included in the primer composition and its makes up 1.0 to 90% by weight of the composition. The bonding agent comprises from 10 to 90% by weight of a methacrylate or acrylate having neither an acidic group nor a hydroxyl group and having at least one unsaturated double bond, and comprises 10 to 90% by weight of the composition. These monomers include methyl methacrylate and ethyl methacrylate (col. 4, lines 44-49), two monomers that qualify as volatile solvents according to page 20 of the instant specification. The bonding agent also comprises an additional monomer without an acidic group but with a hydroxyl group and composes from 10% -90% of the composition. These monomers include 2,2-bis[4-(2-hydroxy-3-methacryloxypropoxy) phenyl]propane and 2-hydroxy-1,3-dimethacryloxypropane (col. 5, lines 41-48), monomers that qualify as polyfunctional monomers, as recited by the instant claims. A

photopolymerization initiator is included in the bonding agent composition and makes up 0.1 to 5.0% by weight of the composition. The disclosed percentages encompass the percentages recited in claim 2. The bonding agent may also comprise a filler, inorganic fillers are preferred, and a silica powder, and a glass powder (e.g., a barium glass powder, a fluoroaluminosilicate glass powder) are particularly preferred. Further, if desired, fillers processed with a surface-treating material such as a silane coupling agent can be used. The dentin is treated with the self-etching primer wherein the (meth)acrylate monomer penetrates into the dentin while decalcifying the dentin. Then, after drying the water-soluble organic solvent in the self-etching primer, the one-pack type bonding agent with superior penetration properties is applied onto a tooth surface. The polymerizable component in the self-etching primer penetrates into the dentin and is integrated with the bonding agent, whereby the resin monomer reliably penetrates into the decalcified dentin. Thus, high-strength adhesion is attained (col. 2,lines 39-57). The photopolymerization of the bonding agent is achieved upon irradiation of active rays such as ultraviolet light or visible rays (col. 6, lines 47-49). The method of applying the disclosed invention encompasses claim 7. In regards to claim 6, the compositions may be applied to teeth in general therefore encompassing bleached or unbleached teeth. The reference differs from the instant claims insofar as it does not teach the viscosity of the compositions ranging from 30cP to 3000 cP at 30 °C.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re

Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have optimized the viscosity motivated by the desire to ensure the compositions stayed on the teeth long enough to provide effective treatment for the teeth.

2) Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsunae et al. (US 6,174,935) as applied to claims 1-2 and 6-7 above in view of Ying (EP 0 173 567).

The primary reference is discussed above in the Obviousness (New rejections) section subsection 1. The photoinitiators of the reference includes camphorquinone and benzil. The dental adhesive kit of the reference can adhere a dental restorative material to a tooth structure firmly and reliably and has superior sealing properties. The composition also is simple to handle (col. 21, lines 14-21). The reference differs from the instant claims insofar as it does not teach using acylphosphine oxides as photopolymerization initiators.

Ying teaches methods of treating teeth with photopolymerizable compositions. The compositions include acylphosphine oxide photoinitiators, which encompasses claim 3. The acylphosphine oxide catalyst system of the disclosed invention provides ultimate properties similar to those, which can be obtained by camphoroquinone/benzil systems, but with added desirable effects. The composition provides an optically clear resin as opposed to the light orange-yellow resin obtained with the camphorquinone system. The catalyst comprises 0.1% to 5% of the composition. The preferred

acylphosphine oxide was 2,4,6-trimethylbenzoyldiphenylphosphine oxide (page 8, lines 25-32), as recited in claim 4. The compositions may also include fillers when making a composite composition. Fillers include silica, powdered glass, and powdered quartz (page 4, lines 7-9). The ingredients of one of the suitable fillers include $Al_2O_3$, $B_2O_3$, BaO and $SiO_2$, similar to those compounds found on page 17 of the instant specification, thereby encompassing claim 10. The compositions also comprise polyfunctional monomers and a preferred aspect of the invention includes monofunctional monomers in conjunction with the above monomers. These monomers may also act as volatile solvents. In the examples of table 1, benzyl methacrylate is incorporated into the compositions at a concentration of 15 parts by weight, about 15% by weight, which encompasses the instant claims for a volatile solvent. The polyfunctional monomer ranges from about 85 to 100 parts by weight (83% to 98%). The reference discloses before the compositions are applied to the teeth, the teeth are etched with acid (page 15). The reference differs from the instant claims insofar as it does not disclose a self-etching primer solution is applied to the teeth before applying the composition.

It would have been obvious to one of ordinary skill in the art to have used the acylphosphine oxide photoinitiator in the compositions of the primary reference motivated by the desire to have a composition that would not cause discoloration of the teeth and would produce a optically clear finish as disclosed by the secondary reference.

3) Claims 8-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki et al. (JP 2002-003327) in view of Nakatsuka et al. (EP 0 980 682).

Haruyuki et al. disclose tooth coating compositions that are to be applied to the teeth after the teeth have been bleached. The coatings are applied to the teeth to inhibit the teeth from reforming stains from foods and plaque. The compositions comprise 8% to 80% of a polyfunctional acrylate monomer, 16% to 80% of a low boiling point solvent, 0.3% to 5% by wt of a light polymerization initiator and titanium dioxide. The method of applying the compositions to the teeth may include preparing the teeth by etching to improve adhesiveness of the coating (paragraph 0046). The reference differs from the instant claims insofar as it does not disclose that a self-etching primer and a coating (bonding) composition are applied to the teeth before applying the composition or the three are in combination in a kit.

Nakatsuka et al. teach bonding compositions for dental use. The compositions have two components, which include a primer composition and an adhesive composition. The primer composition comprises a polymerizable monomer, which makes up 0.000001% to 50% by weight of the composition. The solvent of the primer compositions may be a mixture of water and organic solvents such as ethanol, methanol, acetone and isopropanol (page 13, paragraph 0031) and comprises from 50% to 99.999999% weight of the composition. The bonding agent composition comprises a photopolymerizable monomer such as 2-hyroxyethyl methacrylate, a photopolymerization initiator including acylphosphine oxide such as 2,4,6-

trimethylbenzoylethoxyphenylphosphine oxide (page 13, paragraphs 0037-0038) and a photopolymerizable monomer. One or more of the disclosed monomers may be used in the adhesive compositions (pages 15-16), which encompasses claims 12-13. The bonding agent also comprises fillers such as silica and glass containing $Al_2O_3$, $B_2O_3$ or BaO, encompassing claim 10. The initiator makes up 0.5% to 10% of the composition. The two compositions are added by applying the primer first followed by the bonding agent. The compositions are cured by light. The restoration material is then added to the second composition. The reference differs from the instant claims insofar as it does not disclose a surface smoothing composition as a restorative material that may be used after applying the primer and adhesive compositions.

It would have been obvious to one of ordinary skill in the art to have used the primer and adhesive composition before treating the teeth with the compositions of the primary reference motivated by the desire to have better adhesion of the coating or composite material to the dentin or enamel as disclosed by the secondary reference.

In regards to the viscosity of the coating compositions, it would have been obvious to one of ordinary skill in the art to have optimized the viscosity motivated by the desire to ensure the compositions stayed on the teeth long enough to provide effective treatment for the teeth, as supported by cited precedent above.

4) Claims 8-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki et al. (JP 2002-003327) in view of Matsunae et al. (US 6,174,935).

The primary reference, Haruyuki et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose that a self-etching primer and a coating (bonding) composition are applied to the teeth before applying the composition or the three are in combination in a kit.

The secondary reference, Matsunae et al., is discussed above. The dental kit of the reference is to provide enhanced adhesion to dental restoratives. The monomers used in the bonding agent (coating composition) include 2-hydroxyethyl methacrylate as well as some hydrophobic monomers, encompassing claims 12 and 13. Accordingly, the dental adhesive kit can adhere a dental restorative material to a tooth structure firmly and reliably, has a simple handling from the clinical viewpoint and can provide for stable dental restoration remedy with superior peripheral sealing properties and is free from any anxiety of a secondary caries. The reference differs from the instant claims insofar as it does not disclose a surface smoothing composition as a restorative material that may be used after applying the primer and adhesive compositions.

It would have been obvious to one of ordinary skill in the art to have used the primer and adhesive composition before treating the teeth with the compositions of the primary reference motivated by the desire to have better adhesion of the coating or composite material to the dentin or enamel, use components that are simple to use and inhibits secondary caries, as disclosed by the secondary reference.

In regards to the viscosity of the coating compositions, it would have been obvious to one of ordinary skill in the art to have optimized the viscosity motivated by

the desire to ensure the compositions stayed on the teeth long enough to provide effective treatment for the teeth, as supported by cited precedent above.

Claims 1-4, 6-10 and 12-15 are rejected.

No claims allowed.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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